

claims the original priority date of September 2, 1998.

Rejection under 35 U.S.C. 103(a)

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moser (Compendium on Continuing Education for the Practicing Vet. Vol. 13(4), pp 607-611, 1991), specification at page 2, lines 20-23, MacDonald et al. (Ann. Rev. Nutr., vol. 4, pp 521-62, 1984), Rogers et al. (Enzyme, vol 22, pp 348-56, 1977) or Kealy (U.S. Patent No. 3,930,031), in view of Sunvold (U.S. Patent No. 5,932,258) and Bruno et al. (U.S. Patent No. 6,013,622). The Examiner contends that it is known in the art that the cat's requirements for carbohydrate are minimal, and that it would have been obvious to combine the teachings to optimize diet requirements for the cat.

Initially, Applicant notes that Claims 6, 7, 10, 17, 19, 20 and 21 have been canceled, Claims 11 and 13 have been modified, and new Claims 22-29 have been added. Claims 11, 24, 25, and 28 are now directed to a method of prevention of a disease of abnormal carbohydrate metabolism. Such a disease can include, for example, diabetes mellitus and obesity. Support for the new language regarding preventing development of a disease of abnormal carbohydrate metabolism may be found in the Specification, page 11, lines 1-5: "... the inventor believes that the intake of dietary carbohydrate at levels commonly seen in commercial cat foods can be harmful to the cat, for example by causing depletion and or suppression of insulin secretion, ultimately causing those animals most sensitive to these effects to become clinically diabetic." Applicant presents the following arguments to traverse the rejection made by the Examiner.

For a combination of references cited under 35 U.S.C. 103(a) to be proper, each and every element of the claimed invention must be disclosed by the combination as applied by the Examiner.

Applicant submits that the combination of references, as made by the Examiner does not disclose all of the elements of the claimed invention. In particular, while the references cited by the Examiner teach the general nutritional requirements for obligate carnivores, none of the cited references, alone or in combination, identifies methods or compositions directed to protecting obligate carnivores from a disease of abnormal carbohydrate metabolism. Further, none of the cited references teaches or suggests that feeding a moderate carbohydrate diet to an obligate carnivore, such as a cat, could lead to diseases of abnormal carbohydrate metabolism, and thus do not teach or suggest that feeding a low carbohydrate diet could reduce the severity or cure such a disease. Applicant will discuss all references individually, then will discuss the combination of the references.

The Examiner has characterized Moser (Compendium on Continuing Education for the Practicing Vet. Vol. 13(4), pp 607-611, 1991), as showing that it is known in the art that minimal carbohydrates may be used to treat diabetic cats. Applicant strongly disagrees. Applicant submits that Moser merely discusses a high calorie diet for debilitated animals as a way to increase caloric intake in animals that, due to injury or wasting disease, have higher caloric requirements. Fat is increased in this diet because it has a higher caloric density than carbohydrate, thereby increasing the caloric density of the animal's diet. Carbohydrate reduction is merely secondary, a by-product of increasing fat to increase calories. Further, Moser goes on to say, "diabetic cats should be fed . . . foods with enhanced levels of crude fiber and complex carbohydrates. . ." Such a statement directly teaches away from the Applicant's invention of feeding much lower levels of carbohydrate to an obligate carnivore, rather than enhanced levels of carbohydrate, as taught by Moser. Applicant respectfully submits that Moser, rather than suggesting the present invention, directly teaches away by recommending enhanced

carbohydrate in the diet of diabetic animals. Thus, Applicant submits that the present invention is not suggested by this reference, either alone or in combination with the other references.

Applicant further submits that the specification at page 2, lines 20-23, MacDonald et al. (Ann. Rev. Nutr., vol. 4, pp 521-62, 1984), or Rogers et al. (Enzyme, vol 22, pp 348-56, 1977), merely reiterate what is known in the art regarding obligate carnivores', such as cats', dietary requirements. It is well-known in the art that obligate carnivores normally have a low intake of carbohydrate compared to animals that are omnivores. However, until the present invention, it was not known that feeding a moderate carbohydrate diet to an obligate carnivore, such as a cat, could lead to diseases of abnormal carbohydrate metabolism, nor was it known that feeding a low carbohydrate diet could cure or at least reduce the severity of such a disease. In fact, MacDonald et al. reports at page 530, last 3 lines, that adult cats efficiently utilized most common carbohydrates added to a meat diet, which demonstrates that MacDonald et al. did not appreciate that a high carbohydrate can lead to diseases of abnormal carbohydrate metabolism, as disclosed by the present invention. Before the present invention, obligate carnivores, such as cats, with diseases of abnormal carbohydrate metabolism, such as diabetes or obesity, were treated with diets that actually had increased levels of carbohydrates or levels similar to those found in normal (moderate carbohydrate) diets. Applicant respectfully submits that the present invention is not suggested by these references, either alone or in combination with the other references.

Applicant also submits that Kealy (U.S. Patent No. 3,930,031) contains no teachings or suggestions regarding the importance of relative levels of fat, protein, or carbohydrate in animal diets. Rather, Kealy teaches a method to increase palatability of cat diets by treating the diet with a mixture of

phosphoric acid and citric acid to coat the cat food. Applicant respectfully submits that the present invention is not suggested by this reference either alone or in combination of the other cited references.

The Examiner has characterized Sunvold (U.S. Patent No. 5,932,258) as teaching that diets containing 8-12% fat prevent obesity/diabetes in cats (Official Office Action, page 4, lines 1-2).

Applicant strongly disagrees with the Examiner's characterization of Sunvold and asserts that Sunvold does not teach or suggest the present invention. Rather, Sunvold shows that optimizing foods by using particular grains as a carbohydrate source will cause a lower postprandial rise in blood sugar following a meal. However, the effect that Sunvold shows is only a very moderate decrease in the blood sugar of dogs. Applicant submits that, as was asserted in the Specification, cats and dogs have different responses to carbohydrates since cats, unlike dogs, are obligatory carnivores. Thus, such results in dogs, even if they were to show prevention of disease in dogs, cannot be extrapolated to cats. Further, Sunvold teaches substitution of carbohydrates to adjust blood sugar effects. In effect, those skilled in the art following Sunvold's teachings would be motivated to continue to experiment to find carbohydrate sources that have the effect of lowering postprandial blood sugar rise. However, Sunvold's teaching of optimization of particular grains does not suggest the present invention, which is to almost completely remove carbohydrate from an obligate carnivore's diet to control diseases of abnormal carbohydrate metabolism. Applicant respectfully submits that the present invention is not suggested by this reference either alone or in combination of the other cited references.

Turning to Bruno et al. (U.S. Patent No. 6,013,622), Bruno teaches supplementation of low calorie weight loss diets with certain amino acids to increase concentrations of neuropeptide Y, which has the effect of increasing metabolism and controlling appetite in rabbits. However, as discussed in the

previous paragraph, an obligate carnivore has different dietary requirements from non-carnivores, such as rabbits, and thus results obtained in rabbits cannot be extrapolated to cats. Applicant respectfully submits that this reference teaches away from the present invention. The present invention teaches that protection against a disease of abnormal carbohydrate metabolism occurs in response to lowering the amount of carbohydrate in the diet, in contrast to the Bruno reference, which teaches that it is necessary to supplement the diet with certain amino acids to achieve weight loss. Applicant therefore respectfully submits that the present invention is not suggested by this reference either alone or in combination of the other cited references.

Applicant submits that there is no suggestion in the references, either alone or in combination, to protect obligate carnivores from a disease of abnormal carbohydrate metabolism, such as diabetes or obesity, or prevent such a disease, using a low-carbohydrate diet. In fact, at least some of the references teach away from the present invention: Moser teaches a diet that is enhanced in complex carbohydrates for treatment of diabetes; Sunvold teaches substitution of carbohydrates in the diet with carbohydrate sources that cause less of a postprandial blood sugar rise; and Bruno teaches supplementation of the diet with neuropeptide Y to decrease appetite in order to effect weight loss. With respect to Kealy, MacDonald, and Rogers et al., the Examiner has noted that these references teach diets for cats which disclose preferred percentages of protein and fat, but which do not disclose carbohydrate content. Applicant respectfully argues that such failure to disclose carbohydrate content demonstrates a lack of appreciation in the art regarding the importance of carbohydrate metabolism in obligate carnivores and the potential risk of disease in such animals when fed a moderate carbohydrate diet. As such, there is no suggestion in the references, either alone or in combination, to protect

obligate carnivores from a disease of abnormal carbohydrate metabolism as disclosed by the present invention.

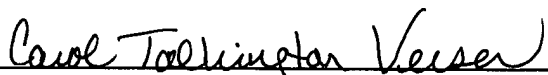
In conclusion, Applicant notes that the Examiner has cited several references that teach the general proposition that obligate carnivores naturally require a diet high in protein and low in carbohydrate. Applicant does not disagree that this general proposition is known to those skilled in the art (see specification page 2, line 3 through page 3, line 6). However, Applicant respectfully argues that knowledge of the dietary requirements of obligate carnivores does not inherently teach that feeding a moderate carbohydrate diet to an obligate carnivore, such as a cat, could lead to diseases of abnormal carbohydrate metabolism, and thus also does not teach or suggest that feeding a low carbohydrate diet could reduce the severity or could cure such a disease. The Examiner is directed to the 1999 Federal Circuit case of *In re Dembiczak*, 50 USPQ2d 1614 (Fed. Cir. 1999), wherein the Federal Circuit admonished the Board of Patent Appeals and Interferences for having “fallen into the hindsight trap”, saying that it is important to observe the “oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field.” Moreover, the Board was told that “combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor’s disclosure as a blueprint for piecing together the prior art to defeat patentability - the essence of hindsight.”

In view of the foregoing amendments and arguments, Applicant respectfully requests allowance of Claims 1-5, 8-9, 11-16, 18, and 22-29.

In view of the foregoing amendments and remarks, Applicant submits that all pending claims are in condition for allowance. Applicant believes that no fees are due. In the event that fees are due, Applicant requests that such fees be debited against Account No. 081930. In the event that the Examiner has any questions regarding Applicant's position, the Examiner is invited to contact the below-named Patent Agent at (970) 493-7272.

Respectfully submitted,

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